CLAYEO C. ARNOLD
A Professional Law Corporation
Clayeo C. Arnold, SBN 65070
Clifford L. Carter, SBN 149621
Kirk J. Wolden, SBN 138902
608 University Avenue
Sacramento, CA 95825
Telephone (916) 924-3100
Fax: (916) 924-1829

Attorney for Plaintiffs

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

SANDRA GREEN, **Plaintiffs,** **vs.** **MERCK & CO., INC., and Does 1 through 25, inclusive,** **Defendants.**	**Case No:** **COMPLAINT FOR PERSONAL INJURIES AND DEMAND FOR JURY TRIAL**

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, Sandra Green through her undersigned attorneys Clayeo C. Arnold, A Professional Law Corporation, sue Defendant Merck & Company, Inc., and allege as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a resident of the State of California, and Defendant is incorporated and has as its primary business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds $75,000.

2. Venue is proper within this district pursuant to Case Management Order No. 3, filed November 1, 2006, signed by John F. Keenan, allowing Fosamax- related cases to be filed directly in the Southern District of New York.

3. Plaintiff, Sandra Green, specifically demands a jury trial.

II. PARTIES

4. Plaintiff, Sandra Green, was born March 21, 1935 At all relevant times Plaintiff was a resident of Cottonwood, California, and used FOSAMAX from February, 2001 until September, 2006.

5. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.

6. Defendant was at all relevant times authorized to conduct business in the State of California and the State of New York.

7. Defendant has regularly transacted business in the State of California and the State of New York and continues to do so.

8. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis.

9. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the State of California for the treatment of pain and inflammation.

10. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of California and in the State of New York.

11. Defendant expected, or should have expected, that its business activities could or would have consequences within the State of California and in the State of New York.

III. SUMMARY OF THE CASE

12. Defendant, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other off-label uses.

13. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff Sandra Green, have suffered and may continue to suffer severe and permanent personal injuries to the jaw bone, including osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw.

14. Defendant concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff Sandra Green, other consumers, and the medical community.

15. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

16. As a result of Defendant's actions and inaction, Plaintiff Sandra Green was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiffs' various injuries and damages. Plaintiffs accordingly seek compensatory damages.

IV. FACTUAL BACKGROUND

17. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

18. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate, which is marketed by Merck as FOSAMAX, for various uses, including the treatment of osteoporosis and Paget's Disease.

19. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

20. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphophonates

include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for FOSAMAX confirms that the molecule contains a nitrogen atom.

21. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have know that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

22. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that Bisphosponates also inhibit vascularization of the affected area and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

23. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turning into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

24. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

25. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and is not reversible.

26. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge,

Defendant failed to implement further study risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

27. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

28. Since FOSAMAX was released, the FDA has received a number of reports osteonecrosis of the jaw among users of FOSAMAX.

29. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

30. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.

31. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

32. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw on patients using FOSAMAX, Defendant continues to defend FOSAMAX and minimize unfavorable findings.

33. FOSAMAX is one of Defendant's top selling drugs. Averaging more than $3 billion a year in sales.

34. Consumers, including Plaintiff Sandra Green, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the conditions.

35. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff Sandra Green, or the medical community, of such risks.

36. As a direct result, Plaintiff Sandra Green was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff Sandra Green requires and will in the future require ongoing medical care and treatment.

37. Plaintiff Sandra Green has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

38. Plaintiff Sandra Green was prescribed and began taking FOSAMAX in February 2001.

39. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

40. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe personal injury to the jaw.

41. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

42. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

43. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

44. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

45. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

COUNTS

COUNT I: NEGLIGENCE

46. Plaintiffs re-allege the above as if fully set forth herein.

47. Defendant owed Plaintiff, Sandra Green, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

48. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b. failing to properly and throughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting FOSAMAX; and

f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

49. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Sandra Green sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

50. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT II: STRICT LIABILITY

51. Plaintiffs re-allege the above.

52. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff Sandra Green.

53. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

54. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

55. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

56. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

57. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

58. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

59. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

60. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

61. As a direct and proximate consequence of Defendant's conduct, Plaintiff Sandra Green sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization,

physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

62. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT III: BREACH OF EXPRESS WARRANTY

63. Plaintiffs re-allege the above.

64. Defendant expressly represented to Plaintiff Sandra Green and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

65. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

66. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

67. Plaintiff Sandra Green, other consumers, and the medical community relied upon Defendant's express warranties.

68. As a direct and proximate result of Defendant's actions, Plaintiff Sandra Green sustained serious significant and permanent injuryof the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of

preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

69. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT IV: BREACH OF IMPLIED WARRANTY

70. Plaintiffs re-allege the above paragraphs.

71. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

72. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

73. Defendant was aware that consumers, including Plaintiff Sandra Green, would use FOSAMAX for treatment of osteoporosis and for other purposes.

74. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

75. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

76. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

77. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

78. As a direct and proximate result of Defendant's action, Plaintiff Sandra Green sustained significant and permanent injuryof the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

79. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT V: FRAUDULENT MISREPRESENTATION

80. Plaintiffs re-allege the above paragraphs.

81. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendant represented that FOSAMAX was safer than other alternative medications.

82. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

83. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

84. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

85. Plaintiff Sandra Green, Plaintiff's doctors, and others relied upon the representations.

86. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

87. As a direct and proximate result, Plaintiff Sandra Green sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

88. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to

punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VI: FRAUDULENT CONCEALMENT

89. Plaintiffs re-allege the above paragraphs.

90. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

91. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.

92. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

93. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

94. Plaintiff Sandra Green, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.

95. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentation, Plaintiff Sandra Green suffered significant and permanent injury of the jaw and was caused to suffer severe and permanent injuries, including pain and mental and physical anguish and suffering, including a diminished capacity

for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has suffered and will continue to suffer a loss of wages and wage-earning capacity and has incurred expense for medical care and treatment due to the injuries caused by FOSAMAX.

96. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendant, as follows:

a. compensatory damages on each cause of action;

b. punitive damages on each cause of action;

c. reasonable attorneys' fees where recoverable;

d. costs of this action; and

e. such other additional and further relief as the Court may deem necessary, appropriate, and just.

VIII. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

Date: July 17, 2007

Respectfully submitted

/s/ - CLIFFORD L. CARTER
CLIFFORD L. CARTER
Attorney for Plaintiff